

## **Remarks**

### **I. Status of the Application and Claims**

As originally filed, the present application had a total of 12 claims. These were all previously cancelled and replaced with claims 13-22. New claims 23-26 were added in a previous response. In response to the final Office Action dated June 12, 2007, Applicant filed an Amendment and Response Under 37 C.F.R. § 1.116 on September 28, 2007 amending claims 13, 23, and 25. Applicant subsequently filed a Supplemental Amendment and Response that was not entered.

After entry of this response, claims 13-26 will be pending in this patent application. In this Response, Applicant has amended claims 13 and 23 to remove the word “endogenous” in the description of the DNA sequence and to recite that overexpression is achieved by “changing a promoter normally found in a galP gene.” Claim 13 has also been amended to clarify an issue with respect to SEQ ID NO:3, and similar conforming amendments have been made to claims 15 and 16. Independent claim 23 has been amended to recite that the bacterium “comprises PTS enzymes.” Finally, dependent claims 21-23 have been amended to clarify the nature of the overexpression and attenuation that are recited. No new matter has been added.

Applicant respectfully requests reconsideration and allowance of this patent application in view of the foregoing amendments and the following remarks.

### **II. The Telephonic Interview**

On February 18, 2009, undersigned conducted a telephonic interview with Examiner Alexander Kim and Supervisory Examiner Jon Weber. During the interview, each point raised in the Office Action was discussed, and it was agreed that the above claim amendments would resolve all of the outstanding issues. Applicant and the undersigned appreciate the thoughtful discussion and suggestions from Examiner Kim and Supervisory Examiner Weber. Additional description of the discussion during the interview is found in the remarks below.

## **The Rejections**

### **III. Rejection of Claims Under 35 U.S.C. § 112, Second Paragraph**

#### A. Claims 13 and 23

On page 4 of the Office Action, in paragraph 9, the Examiner rejects claims 13-26 as allegedly being indefinite under 35 U.S.C. § 112, second paragraph. The Examiner asserts in particular that with respect to independent claims 13 and 23, “It is unclear how any Enterobacteriaceae family other than E. coli can comprises [*sic*] overexpressed endogenous DNA of SEQ ID NO:3, or a DNA encoding SEQ ID NO:4.” As was agreed during the interview, Applicant has now removed the term “endogenous” from the claims. Therefore, Applicant respectfully submits that the rejection should be withdrawn.

#### B. Claims 21 and 22 – Antecedent Basis

On page 6 of the Office Action, in paragraph 10, the Examiner rejects claims 21 and 22 as allegedly being indefinite under 35 U.S.C. § 112, second paragraph. The Examiner asserts that the use of the definite article “the” when listing the genes renders those two claims indefinite because there is insufficient antecedent basis.

As discussed during the interview, Applicant has amended claims 21 and 22 to use the indefinite article “a.” Accordingly, Applicant respectfully requests that the rejection be withdrawn.

### **IV. Rejection of Claims Under 35 U.S.C. § 112, First Paragraph**

#### A. Claim 23 – New Matter

On page 7 of the Office Action, in paragraph 11, the Examiner rejects claim 23 under 35 U.S.C. § 112, first paragraph, as allegedly containing new matter. In particular, the Examiner asserts that the recitation that the bacterium “transports glucose by a PEP-dependent phosphotransferase (PTS) pathway” in claim 23 is not supported by the original disclosure.

Applicant respectfully disagrees. Applicant’s specification makes specific mention of “PTS enzymes” which may be overexpressed in addition to galP, and believes that that specific mention does support the phrase that the Examiner notes in claim 23. As the Examiner has

agreed in paragraph 14, on page 13 of the Office Action, there is only one PTS pathway, and it is well known in the art. Therefore, a reference to PTS enzymes is inherently a reference to that pathway, whose well-known purpose is to transport glucose.

However, Applicant wishes to expedite prosecution. Therefore, as suggested by Supervisory Examiner Weber, Applicant has now amended claim 23 to recite that the bacterium “comprises PTS enzymes,” in order to better reflect the exact wording of the specification. Accordingly, Applicant respectfully requests that the rejection be withdrawn.

#### B. Claims 21 and 22 – Written Description and Enablement

On page 8 of the Office Action in paragraph 12, the Examiner rejects claims 21 and 22 as allegedly lacking written description in Applicant’s specification. Additionally, on page 13, in paragraph 13, the Examiner rejects claims 21 and 22 as allegedly lacking enablement. Applicant traverses both of these rejections in view of the claims as amended.

During the telephonic interview, Examiner Kim stated that the rejection was made because of the breadth of the terms “overexpresses” in claim 21 and “attenuated” in claim 22. The Examiner pointed out that while independent claim 13 specifically recites a method of overexpression for the galP gene, there is no such limitation on the methods of overexpression or attenuation for the genes of claims 21 and 22. Therefore, as was agreed during the interview, Applicant has specified that the “overexpression is achieved by one or more methods selected from the group consisting of increasing copy number, using a strong promoter, and mutating the ribosome binding site” which comports with the general definition of overexpression in lines 6-8 of page 11. Applicant has also replaced the word “attenuated” in claim 22 with the word “deleted,” which comports with the specification’s description of attenuation as “switching off” on page 16, at line 21.

Additionally, Applicant notes that the listing of each and every gene in the specification includes a citation to a reference describing the gene. References that generally describe the processes are also cited, and each of those references is incorporated by reference by the statement on line 6 of page 21 of the specification. Therefore, Applicant respectfully submits that claims 21 and 22 are broadly supported.

Accordingly, Applicant respectfully submits that the rejection should be withdrawn.

**V. Rejection of Claims Under 35 U.S.C. § 102**

**A. Rejection of claims 13-16 and 18-20 Under 35 U.S.C. § 102(b)**

On page 14 of the Office Action, in paragraph 16, the Examiner rejects claims 13-16 and 18-20 under 35 U.S.C. § 102(b) as allegedly being anticipated by Valle *et al.*, U.S. Patent Application Publication No. 2002/0155521, as evidenced by Blattner *et al.*, *Science* 277:1453-1474 (1997).

In making the rejection, the Examiner construes claim 13 oddly at the bottom of page 15 of the Office Action. Specifically, the Examiner appears to be asserting that “the claimed process does not require the bacterium must present the nucleotide sequence of SEQ ID NO:3 (i.e., the entire nucleotide sequence of SEQ ID NO:3); wherein the SEQ ID NO:3 is recited in Claims 13, 15 and 16.” That assertion is apparently based on the Examiner’s position that the entire SEQ ID NO:3 does not encode the amino acid sequence of SEQ ID NO:4.

As was discussed during the interview, the Examiner is correct that as presented in the specification, only a portion of SEQ ID NO:3 encodes the amino acid sequence of SEQ ID NO:4. Specifically, as presented in the sequence listing, SEQ ID NO:3 includes synthetic portions. Therefore, to eliminate any potential confusion, Applicant has amended claims 13, 15, and 16 to recite “residues 33-1427 of SEQ ID NO:3,” what the Examiner refers to as the “coding region” of that sequence. As was agreed, that amendment should obviate the issue that the Examiner notes.

As for the Valle, *et al.* reference, the Examiner asserts that the reference discloses overexpressing galP in Example 5 on page 8 of the reference. That is not what Valle, *et al.* discloses. In Example 5 on page 8, the reference discloses taking bacteria in which the galP gene has previously been interrupted, repressed, or blocked, and partially de-repressing it by inactivating the galR and galS genes. Clearly, overexpressing a gene or gene product in a bacterium with a normal metabolism is not the same thing as partially reactivating a normal metabolic pathway in a bacterium in which that pathway has previously been deliberately repressed or blocked.

The Examiner appears to be basing the rejection, in part, on a broad reading of the term overexpression, as defined by Applicant's specification. In response, as was discussed during the interview, Applicant has amended claims 13 and 23 to recite that the "overexpression is achieved by increasing the copy number of said DNA or by changing a promoter normally found in a galP gene," language found in Applicant's specification on page 2 at lines 16-17. As explained above, the Valle *et al.* reference is not changing the promoter normally found in the galP gene. Accordingly, Applicant submits that the rejection has been overcome and should be withdrawn.

B. Rejection of claims 13-14 and 17-20 under 35 U.S.C. § 102(a) over Hernandez-Montalvo, *et al.*

On page 17 of the Office Action, in paragraph 17, the Examiner rejects claims 13-14 and 17-20 under 35 U.S.C. § 102(a) over Hernandez-Montalvo, *et al.*, *Biotechnol. Bioeng.* 83:687-694 (Sept. 20, 2003) as evidenced by Blattner *et al.*

Applicant has previously argued that the Hernandez-Montalvo, *et al.* reference is not prior art, and also previously submitted a certified translation of the priority document to overcome the reference. As was explained in previous responses, the German priority document does not itself include sequence listings, but does disclose, in the form of references and database accession numbers, where to find the nucleotide and amino acid sequences of galP on at least page 6 of the translation.

However, on page 18 of the Office Action, the Examiner notes that SEQ ID NO:3 includes synthetic sequences, and asserts that the priority document does not describe or support those sequences. In response, as described above, Applicant has amended claims 13, 15, and 16 to recite "residues 33-1427 of SEQ ID NO:3," what the Examiner refers to as the "coding region" of SEQ ID NO:3. Regardless of what the priority document may or may not disclose with respect to specific primer or synthetic sequences, the priority document does support the so-called "coding region" of residues 33-1427 of SEQ ID NO:3, which is the nucleic acid sequence of endogenous galP. Therefore, as amended, the rejected claims are supported by the priority document. Thus, Hernandez-Montalvo *et al.* is not prior art, and the rejection

should be withdrawn.

#### **VI. Rejection of Claims Under 35 U.S.C. § 103(a)**

On page 20 of the Office Action, in paragraph 18, the Examiner rejects claim 21 over Valle, *et al.* in view of Debavov, *et al.* U.S. Patent No. 5,705,371. On page 22 of the Office Action, in paragraph 19, the Examiner rejects claim 22 over Valle, *et al.* in view of Debavov, *et al.* Applicant respectfully traverses these rejections.

As Applicant explained above, Valle, *et al.* does not disclose or suggest the method of claim 13, from which claims 21 and 22 depend. Debavov, *et al.* does not remedy the deficiencies of Valle, *et al.* Therefore, Applicant respectfully submits that claims 21 and 22 are patentable at least because of their dependency, and requests that the rejection be withdrawn.

#### **Conclusion**

All objections and rejections having been addressed, Applicant respectfully submits that this application is in condition for allowance, and a timely notice to that effect is earnestly solicited. If, in the opinion of the Examiner, a phone call may help to expedite the prosecution of this application, the Examiner is invited to contact the undersigned.

Respectfully submitted,

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